IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	09/973,088	Confirmation No. 4800
Applicant	:	Marie B. CONNETT-PORCEDDU	
Filed	:	10 October 2001	
TC/A.U.	:	1638	
Examiner	:	Stuart F. Baum	
Docket No.	:	2411-110	
Customer No.	:	6449	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER RULE 132 OF JAMES E. MANN

Dear Sir:

I, James E. Mann, declare as follows:

1. My education and experience are as follows. I received a Bachelor of Science degree in Biology and Chemistry from Shorter College in 1991, a Masters of Science degree in Entomology from Clemson University in 1993, a Doctorate degree in Entomology from Clemson University in 1995 and a Masters of Business Administration from the University of Missouri in 2001. I have been employed by ArborGen, LLC, which is a joint venture including Westvaco Corporation, the assignee of the present application, from 2001 to present as a Director, Finance and Business Development. I was employed by Monsanto Company from 1996 to 2001, first as a Marketing Manager and then as Director, Business Development.

2. While at Monsanto, I led the marketing and business development efforts for biotech cotton in the United States, Mexico and Australia. At ArborGen, I am responsible for leading all business development and licensing activities, including our current somatic embryogenesis production business, which includes somatic embryogenesis of transgenic tissue. My professional background and experience have given me a good and understanding of conifer somatic embryogenesis production and its commercial potential. Accordingly, I believe that I am well

qualified to render a professional opinion regarding the commercial success of conifer somatic embryogenesis of conifers, including transgenic conifers.

3. I understand that the claims recite (a) a method for regenerating transgenic plants of pine of the genus *Pinus* subgenus *Pinus* (claims 1-9 and 11-38), (b) a method for minimizing damage to transformed cell of the pine of the genus *Pinus* subgenus *Pinus* following infection by *Agrobacterium* (claims 39-43 and 45), (c) a method for pine cell tissue culture of pine cells of the genus *Pinus* subgenus *Pinus* (claims 46-51), (d) a method for selecting transformed cells of pine of the genus *Pinus* subgenus *Pinus* (claims 52-57), and (e) a method for eradicating *Agrobacterium* from cells of pine of the genus *Pinus* subgenus *Pinus* (claims 58-62). The method of claims 1-9 and 11-38 provides for enhanced transformation and regeneration of transformed embryogenic pine tissue in which the pine is of the genus *Pinus* subgenus *Pinus*. The remaining methods relate to various aspect of this method. I also understand that the claims of related copending patent application Serial No. 09/973,089 recite a method for regenerating genetically modified plants of pine of the genus *Pinus* selected from the group consisting of Southern yellow pines and hybrids thereof using an improved selection method. This method provides for enhanced regeneration of transgenic embryogenic pine cells for this important group of pines.

4. I understand that the Examiner contends that the invention of the present application, regeneration of transformed embryogenic hard pine (i.e., pines of the subgenus *Pinus*, e.g., *Pinus taeda*), would have been obvious over Levee et al. (*Molecular Breeding* 5:429-440, 1999) which describes the regeneration of transformed embryogenic soft pine (i.e., pines of the subgenus *Strobus*, e.g., *Pinus strobus*). I also have been advised that Levee et al. does not disclose the transformation and regeneration of pine of the subgenus *Pinus*.

5. I have been asked to provide this Declaration concerning commercial success of the methods described and claimed in the present application, as well as those described and claimed in patent application Serial No. 09/973,089.

6. The hard pines (i.e., pines of the subgenus *Pinus*), in particular loblolly pine (*P. taeda*, a Southern yellow pine), its elite lines and hybrids, but also including *P. rigida* and *P. radiata*, are the most commercially important pines, and loblolly pine is the most used species of hard pines. Specifically, loblolly pine is the most widely planted plantation forest species in the world with over

one billion trees planted annually in more than half a dozen countries worldwide. Radiata pine is equally important with over four million hectares already in industrial plantations in more than half a dozen countries worldwide.

7. I have reviewed the Declaration Under Rule 132 of Dr. David Canavera (that is being filed concurrently herewith) concerning the long-felt need in the art for the transformation and regeneration of transformed tissue of pines of the subgenus *Pinus* and the failed attempts of others to meet this need. I agree with his opinion that there was a long felt need to develop improved methods of *Agrobacterium* transformation of hard pines and improved selection of transformed tissue of hard pines, and to develop methods to regenerate *Agrobacterium*-transformed hard pines. I also agree with his opinion that this long felt need was not satisfied by transformation of other conifers, such as white pines and spruces, but was only satisfied by the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089.

8. In addition, ArborGen since its founding has wanted to obtain protocols that would lead to a robust, commercializable system for repeatable, reliable pine transformation followed by efficient selection and embryo development/regeneration, and would be willing to use such protocols developed by anyone. However, since such protocols do not exist elsewhere, including within universities, such as North Carolina State University, institutions, such as Institute of Paper Science and Technology, or the Canadian Forest Service, ArborGen has licensed the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089.

9. ArborGen is using these methods in (a) pre-commercial trials toward the development of ArborGen's commercial products in improved pulping and (b) a gene testing pipeline that is unique because up to 30-60 genes involved in wood development per year can be tested repeatedly in elite genotypes of a conifer species. ArborGen is managing and actively measuring and using field trials, on two different managed field sites and in propagation hedges, of pine plants that arose from material cultured, transformed, selected and embryos developed and regenerated according to the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089.

10. In addition to ArborGen's licensing and commercial use of the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089, ArborGen has been approached by other researchers desiring deals in which ArbroGen would use the methods described

and claimed in patent application Serial Nos. 09/973,088 and 09/973,089 to prepare transgenic hard pines with the genes of interest to these researchers in order to test the expression of genes in pine, especially loblolly pine. These researchers include researchers from a variety of U.S. universities, including North Carolina State University and the University of Florida, researchers from the Canadian Forest Service and Institute of Paper Science and Technology, researchers at European universities and researchers from private companies. For example, AborGen has been approached by researchers who are interested in downregulating a certain gene using RNAi. In order to do RNAi on a pine gene, these researchers need to have working pine transformation system which is only available by the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089. The fact that various researchers have approached ArborGen about using the transformation system of the methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089 is evidence of the commercial value of these methods and is also further evidence that there is no other efficient method to for pine transformation and regeneration of transformed tissue.

11. These facts demonstrate the commercial success of methods described and claimed in patent application Serial Nos. 09/973,088 and 09/973,089.

12. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or of any patent issued thereon.

4/13/04
Date

James E. Mann

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DECLARATION UNDER RULE 132 OF DAVID S. CANAVERA

Dear Sir:

I, David S. Canavera, declare as follows:

1. My education and experience are as follows. I received a Bachelor of Science degree in Forest Management from Michigan Technological University in 1965 and a Masters of Science degree and a Doctorate degree in Forest Tree Improvement from Michigan State University in 1967 and 1969, respectively. I have been employed by MeadWestvaco Corporation from 1980 to the present. From 1998 to 2002, I have been Director of Forest Research, and I am currently Director of Tree Improvement and Technology at MeadWestvaco. Prior to joining MeadWestvaco, I was Associate Professor of Forest Resources at the University of Maine from 1974 to 1980 and Assistant Professor of Forestry at Tuskegee University from 1972-1974. For several years during my employment at MeadWestvaco, I was also an Adjunct Associate Professor in the Department of Forestry at Clemson University.

2. My experience at MeadWestvaco has involved leading our genetics and biotechnology research programs. In tree improvement, our major research thrusts were developing advanced-generation breeding strategies for loblolly pine and enhancing the genetic quality of seed orchard seed; and development of germplasm for hybrid pines, sweetgum, and cottonwood and other Populus hybrids. In biotechnology, the work focused on pine somatic embryogenesis, conifer

micropropagation, and pine rooted cuttings; and many areas of molecular biology including genetic transformation of pines and hardwoods, the use of DNA markers in breeding programs, the development of flowering control in trees, stress resistance and development of herbicide resistant trees. Accordingly, I believe that I am well qualified to consider long felt needs in the transformation and regeneration of hard pines.

3. I understand that the claims of the present application recite (a) a method for regenerating transgenic plants of pine of the genus *Pinus* subgenus *Pinus* (claims 1-9 and 11-38), (b) a method for minimizing damage to transformed cell of the pine of the genus *Pinus* subgenus *Pinus* following infection by *Agrobacterium* (claims 39-43 and 45), (c) a method for pine cell tissue culture of pine cells of the genus *Pinus* subgenus *Pinus* (claims 46-51), (d) a method for selecting transformed cells of pine of the genus *Pinus* subgenus *Pinus* (claims 52-57), and (e) a method for eradicating *Agrobacterium* from cells of pine of the genus *Pinus* subgenus *Pinus* (claims 58-62). The method of claims 1-9 and 11-38 provides for enhanced transformation and regeneration of transformed embryogenic pine tissue in which the pine is of the genus *Pinus* subgenus *Pinus*. The remaining methods relate to various aspect of this method. I also understand that the claims of related copending patent application Serial No. 09/973,089 recite a method for regenerating genetically modified plants of pine of the genus *Pinus* selected from the group consisting of Southern yellow pines and hybrids thereof using an improved selection method. This method provides for enhanced regeneration of transgenic embryogenic pine cells for this important group of pines.

4. I understand that the Examiner contends that the invention of the present application, regeneration of transformed embryogenic hard pine (i.e., pines of the subgenus *Pinus*, e.g., *Pinus taeda*), would have been obvious over Levee et al. (*Molecular Breeding* 5:429-440, 1999) which describes the regeneration of transformed embryogenic soft pine (i.e., pines of the subgenus *Strobus*, e.g., *Pinus strobus*). I also have been advised that Levee et al. does not disclose the transformation and regeneration of pine of the subgenus *Pinus*.

5. I have been asked to provide this Declaration concerning a long-felt need in the art for the transformation and regeneration of transformed tissue of pines of the subgenus *Pinus* and the failed attempts of others to meet this need.

6. The hard pines (i.e., pines of the subgenus *Pinus*), in particular loblolly pine (*P. taeda*, a Southern yellow pine), its elite lines and hybrids, but also including *P. rigida* and *P. radiata*, are the most commercially important pines, and loblolly pine is the most used species of hard pines. Thus, transformation followed by reliable regeneration of the hard pines is more desirable than transformation and regeneration of other conifers, such as white pines (e.g., pines of the subgenus *Strobus*) and spruces. The transformation and regeneration of hard pines has turned out to be more difficult than the transformation and regeneration of other conifers.

7. Researchers have been attempting to transform hard pines with *Agrobacterium* followed by reliable regeneration of the transformed tissue since about 1988-1989. Such research has been conducted in many laboratories, including for example, North Carolina State University, the Institute of Paper Science and Technology, the Canadian Forest Service, International Paper and Westvaco Corporation. During this period, regeneration systems for non-transformed hard pines had been developed. Evidence of the development of regeneration systems for hard pines is illustrated by Handley (U.S. Patent No. 5,491,090; copy attached as Exhibit 1). Although hard pines had been transformed using *Agrobacterium*, regeneration of *Agrobacterium*-transformed hard pines had not been achieved despite considerable effort over this time frame. Evidence that regeneration of *Agrobacterium*-transformed hard pines had not been achieved is illustrated by Wenck et al. (1999, *Plant Mol Biol* **39**:407-416; copy attached as Exhibit 2) which specifically states "[w]e have not been able to recover stable transformants through selection to date." See page 413, bottom of left column with respect to loblolly pine, a hard pine. The experiments of others did not result in regenerated transgenic hard pine, such as loblolly pine, plants as evidenced by Wenck et al. and the dearth of published reports on regenerated transformed loblolly pine plants. Thus, there was a long-felt need to develop improved methods of *Agrobacterium* transformation of hard pines and improved selection of transformed tissue of hard pines, and to develop methods to regenerate *Agrobacterium*-transformed hard pines. This long felt need was not satisfied by transformation of other conifers, such as white pines and spruces.

8. The method for hard pine transformation and regeneration described and claimed in patent application Serial No. 09/973,088 and the method for selection of transgenic Southern yellow pine tissue described and claimed in patent application Serial No. 09/973,089 are the first methods

which achieved reliable and efficient regeneration of transgenic hard pine plants, i.e., the regeneration of transformed hard pine tissue. This reliable and efficient regeneration of transgenic hard pine results directly from the methods described and claimed in these applications. The methods described and claimed in these patent applications are sufficiently robust to fill the long-held need because they result in the regeneration of transgenic hard pines and they have been shown to be valid for a wide variety of genotypes, including multiple species of hard pines, and even lines from within elite families of loblolly pine such as those being tested by MeadWestvaco Corporation for commercial deployment. Without these methods, reliable and efficient regeneration of transgenic hard pine had not been achieved. Thus, these methods meet the long-felt need of providing regenerated *Agrobacterium*-transformed hard pines.

9. In addition, a method such as the one use by the Canadian Forest Service that is not able to be used for multiple species did not meet the long felt need for regeneration of transgenic hard pines. Thus, the method described and claimed in patent application Serial No. 09/973,088 enabling regeneration of transgenic hard pines does satisfy this long-held need. Furthermore, a method that did not enable selection even from within elite families of loblolly pine would not meet the long felt need. Thus, the method described and claimed in patent application Serial No. 09/973,089 enabling selection even from within elite families of loblolly pine does satisfy this long-held need.

10. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or of any patent issued thereon.

2/13/2004
Date

David L. Canavera
David S. Canavera